

AMENDED IN ASSEMBLY JUNE 23, 2015

AMENDED IN ASSEMBLY JUNE 8, 2015

SENATE BILL

No. 225

Introduced by Senator Wieckowski

February 13, 2015

An act to amend Sections ~~117630~~ 117630, 117700, 117935, 117960, 118040, and 118275 of the Health and Safety Code, relating to medical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 225, as amended, Wieckowski. Medical waste.

Existing

(1) *Existing* law, the Medical Waste Management Act, regulates the disposal of medical waste, including requiring specified biohazard materials to be disposed of in biohazard bags and requiring specified treatment for medical waste. Transportation, storage, treatment, or disposal of medical waste in a manner not authorized by the act is a crime. Existing law defines specified terms for purposes of the Medical Waste Management Act, including “biohazard bag.” Existing law defines a biohazard bag to mean a film bag that is impervious to moisture. Existing law requires the film bags that are used for transport to be marked and certified by the manufacturer as having passed specified tests prescribed for tear resistance and for impact resistance. Existing law also imposes a specified labeling requirement on containers for nonradioactive pharmaceutical wastes that are not subject to a specified federal law and that are regulated as medical waste.

This bill would *revise the definition of “biohazard bag” and would* limit the application of the requirement that film bags used for transport be marked and certified by the manufacturer as having passed specified

tests only to those film bags that are used for transport from the generator's facility onto ~~roadways~~. *roadways and into commerce to a treatment and disposal facility. The bill would revise the requirements for film bags that are used to collect medical waste within a facility and small biohazard bags, as specified.* The bill would also make a clarifying change to the labeling requirement for containers for nonradioactive pharmaceutical waste.

(2) Existing law defines medical waste and specifically excludes from that definition hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste.

This bill would exclude controlled substances from the definition of medical waste.

(3) Existing law requires small and large quantity generators to file with the enforcement agency a medical waste management plan containing specified information, including, if applicable, the steps taken to categorize the pharmaceutical wastes generated at the facility to ensure that the wastes are properly disposed of as prescribed.

This bill would remove the requirement that the waste management plans include the steps taken to categorize the pharmaceutical wastes generated at the facility.

(4) Existing law requires a hazardous waste transporter or generator transporting medical waste to maintain a completed shipping document in compliance with the United States Department of Transportation and a tracking document if the waste is transported to a facility other than the final medical waste treatment facility.

This bill would require a shipping document only when a hazardous waste transporter transports medical waste on a public roadway. The bill would also require the shipping document and tracking information to be maintained only by hazardous waste transporters, and not by generators transporting waste.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 117630 of the Health and Safety Code
2 is amended to read:
3 117630. (a) "Biohazard bag" means a disposable film bag ~~that~~
4 ~~is impervious to moisture.~~ *used to contain medical waste.* The film
5 bags that are used to line the United States Department of

Transportation (USDOT)-approved shipping containers for transport from the generator's facility onto roadways and into commerce to a treatment and disposal facility shall be marked and certified by the manufacturer as having passed the tests prescribed for tear resistance in the American Society for Testing Materials (ASTM) D1922, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method" and for impact resistance in ASTM D1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method," as those documents were published on January 1, 2014. The film bag shall meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both parallel and perpendicular planes with respect to the length of the bag. The color of the bag shall be red, except when yellow bags are used to further segregate trace chemotherapy waste and white bags are used to further segregate pathology waste.

(b) The film bag that is used to collect medical waste within a facility shall only be required to be marked and certified by the manufacturer to meet the ASTM D1709 dart drop test, provided that when the bag is prepared for transport off-site, it is placed into a USDOT-approved container lined with a biohazard bag that is ASTM D1709 and ASTM D1922 certified.

(c) Small biohazard bags used for the collection of medical waste in small waste containers, including, but not limited to, exam and patient rooms, kickbuckets, and benchtop waste containers, shall not be required to be ASTM D1709 or ASTM D1922 certified, provided that the bag has strength sufficient to preclude ripping, tearing, leaking, or bursting under normal conditions and the bags from these containers are placed into a larger container lined with an ASTM D1709 marked and certified film bag or a USDOT-approved shipping container lined with an ASTM D1709 and ASTM D1922 certified bag.

(d) The color of the bag shall be red, except when yellow bags are used to further segregate trace chemotherapy waste and white bags are used to further segregate pathology waste. The biohazard bag shall be marked with the international biohazard symbol and may be labeled as regulated medical waste, biomedical waste, biohazardous waste, infectious waste, clinical waste, infectious substance, or other language as authorized by the USDOT.

1 *SEC. 2. Section 117700 of the Health and Safety Code is*
2 *amended to read:*

3 117700. Medical waste does not include any of the following:

4 (a) Waste generated in food processing or biotechnology that
5 does not contain an infectious agent, as defined in Section 117675,
6 or an agent capable of causing an infection that is highly
7 communicable, as defined in Section 117665.

8 (b) Waste generated in biotechnology that does not contain
9 human blood or blood products or animal blood or blood products
10 suspected of being contaminated with infectious agents known to
11 be communicable to humans or a highly communicable disease.

12 (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,
13 or vomitus, unless it contains visible or recognizable fluid blood,
14 as provided in subparagraph (C) of paragraph (1) of subdivision
15 (b) of Section 117690.

16 (d) Waste ~~which~~ *that* is not biohazardous, such as paper towels,
17 paper products, articles containing nonfluid blood, and other
18 medical solid waste products commonly found in the facilities of
19 medical waste generators.

20 (e) Hazardous waste, radioactive waste, or household waste,
21 including, but not limited to, home-generated sharps waste, as
22 defined in Section 117671, *and controlled substances*.

23 (f) Waste generated from normal and legal veterinarian,
24 agricultural, and animal livestock management practices on a farm
25 or ranch unless otherwise specified in law.

26 *SEC. 3. Section 117935 of the Health and Safety Code is*
27 *amended to read:*

28 117935. A small quantity generator required to register with
29 the enforcement agency pursuant to Section 117930 shall file with
30 the enforcement agency a medical waste management plan on
31 forms prescribed by the enforcement agency, if provided. The
32 plans shall contain, but are not limited to, all of the following:

33 (a) The name of the person.

34 (b) The business address of the person.

35 (c) The type of business.

36 (d) The types, and the estimated average monthly quantity, of
37 medical waste generated.

38 (e) The type of treatment used onsite.

39 (f) The name and business address of the registered hazardous
40 waste hauler used by the generator for backup treatment and

1 disposal, for waste when the onsite treatment method is not
2 appropriate due to the hazardous or radioactive characteristics of
3 the waste.

4 (g) The name of the registered hazardous waste hauler used by
5 the generator to have untreated medical waste removed for
6 treatment and disposal, if applicable.

7 (h) The name of the common carrier used by the generator to
8 transport pharmaceutical waste offsite for treatment and disposal
9 pursuant to Section 118032, if applicable.

10 (i) ~~If applicable, the steps taken to categorize the pharmaceutical~~
11 ~~wastes generated at the facility to ensure that the wastes are~~
12 ~~properly disposed of as follows:~~

13 ~~(1) Pharmaceutical wastes classified by the federal Drug~~
14 ~~Enforcement Agency (DEA) as “controlled substances” are~~
15 ~~disposed of in compliance with DEA requirements.~~

16 ~~(2) The name and business address of the registered hazardous~~
17 ~~waste hauler used by the generator to have wastes that are not~~
18 ~~regulated pursuant to the federal Resource Conservation and~~
19 ~~Recovery Act of 1976 and nonradioactive pharmaceutical wastes~~
20 ~~regulated as medical waste safely removed for treatment in~~
21 ~~compliance with subdivision (b) of Section 118222 as waste~~
22 ~~requiring specific methods.~~

23 ~~(j)~~
24 (i) A closure plan for the termination of treatment at the facility
25 using, at a minimum, one of the methods of decontamination
26 specified in subdivision (a) or (b) of Section 118295, thereby
27 rendering the property to an acceptable sanitary condition following
28 the completion of treatment services at the site.

29 ~~(k)~~
30 (j) A statement certifying that the information provided is
31 complete and accurate.

32 *SEC. 4. Section 117960 of the Health and Safety Code is*
33 *amended to read:*

34 117960. A large quantity generator required to register with
35 the enforcement agency shall file with the enforcement agency a
36 medical waste management plan, on forms prescribed by the
37 enforcement agency, if provided. The plans shall contain, but are
38 not limited to, all of the following:

39 (a) The name of the person.

40 (b) The business address of the person.

1 (c) The type of business.

2 (d) The types, and the estimated average monthly quantity, of
3 medical waste generated.

4 (e) The type of treatment used onsite, if applicable. For
5 generators with onsite medical waste treatment facilities, the
6 treatment capacity of the onsite treatment facility.

7 (f) The name and business address of the registered hazardous
8 waste hauler used by the generator to have untreated medical waste
9 removed for treatment, if applicable, and, if applicable, the name
10 and business address of the common carrier transporting
11 pharmaceutical waste pursuant to Section 118032.

12 (g) The name and business address of the offsite medical waste
13 treatment facility to which the medical waste is being hauled, if
14 applicable.

15 (h) An emergency action plan complying with regulations
16 adopted by the department.

17 ~~(i) If applicable, the steps taken to categorize the pharmaceutical~~
18 ~~wastes generated at the facility to ensure that the wastes are~~
19 ~~properly disposed of as follows:~~

20 ~~(1) Pharmaceutical wastes classified by the federal Drug~~
21 ~~Enforcement Agency (DEA) as “controlled substances” are~~
22 ~~disposed of in compliance with DEA requirements.~~

23 ~~(2) The name and business address of the hazardous waste hauler~~
24 ~~used by the generator to have wastes that are not regulated pursuant~~
25 ~~to the federal Resource Conservation and Recovery Act of 1976~~
26 ~~and nonradioactive pharmaceutical wastes regulated as medical~~
27 ~~wastes safely removed for treatment in compliance with subdivision~~
28 ~~(b) of Section 118222, as waste requiring specific methods.~~

29 ~~(j)~~

30 (i) A closure plan for the termination of treatment at the facility
31 using, at a minimum, one of the methods of decontamination
32 specified in subdivision (a) or (b) of Section 118295, thereby
33 rendering the property to an acceptable sanitary condition following
34 the completion of treatment services at the site.

35 ~~(k)~~

36 (j) A statement certifying that the information provided is
37 complete and accurate.

38 *SEC. 5. Section 118040 of the Health and Safety Code is*
39 *amended to read:*

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter ~~or generator~~ transporting medical waste shall maintain a completed shipping document in compliance with United States Department of Transportation (USDOT) requirements when medical waste is transported *on a public roadway*. In addition to the shipping document required by USDOT, a hazardous waste transporter ~~or generator~~ who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents ~~which show~~ *information that shows* the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the shipping *document* and tracking ~~documents~~ *document, if the waste is transported to a facility other than the final medical waste treatment facility* for the generator's medical waste records. *Information from the shipping document and the tracking document may be combined onto one form having the required information.* The transporter ~~or generator~~ transporting medical waste shall maintain its copy of the ~~shipping and tracking~~ *shipping, tracking, and combined* documents for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to ~~Section 118030~~ *Section 117946 or 117976*.

(2) The type of medical waste transported and the quantity or aggregate weight of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) ~~Any~~ A hazardous waste transporter or generator transporting medical waste in a vehicle shall have the shipping and tracking documents in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original shipping and tracking documents.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

~~SEC. 2.~~

SEC. 6. Section 118275 of the Health and Safety Code is amended to read:

118275. (a) To containerize or store medical waste, at the point of generation and while collected in that room, a person shall do all of the following:

(1) Medical waste, as defined in Section 117690, shall be contained separately from other waste at the point of origin in the producing facility. Sharps containers may be placed in biohazard bags or in containers with biohazard bags.

(2) Biohazardous waste, as defined in paragraph (1) of subdivision (b) of Section 117690, shall be placed in a biohazard bag ~~conspicuously labeled with the words "Biohazardous Waste" or with the international biohazard symbol and the word "BIOHAZARD."~~ *and labeled in compliance with Section 117630.*

(3) Sharps waste, as defined in paragraph (4) of subdivision (b) of Section 117690, including sharps and pharmaceutical waste containerized pursuant to paragraph (7), shall be contained in a United States Food and Drug Administration (USFDA) approved sharps container that meets USFDA labeling requirements and is handled pursuant to Section 118285.

(4) Trace chemotherapy waste, as defined in paragraph (5) of subdivision (b) of Section 117690, shall be segregated for storage, and, when placed in a secondary container, that container shall be

1 labeled with the words “Chemotherapy Waste,” “CHEMO,” or
2 other label approved by the department on the lid and sides, so as
3 to be visible from any lateral direction, to ensure treatment of the
4 biohazardous waste pursuant to Section 118222. Sharps waste that
5 is contaminated through contact with, or having previously
6 contained, chemotherapeutic agents, shall be placed in sharps
7 containers labeled in accordance with the industry standard with
8 the words “Chemotherapy Waste,” “CHEMO,” or other label
9 approved by the department, and shall be segregated to ensure
10 treatment of the sharps waste pursuant to Section 118222.

11 (5) Pathology waste, as defined in paragraph (2) of subdivision
12 (b) of Section 117690, shall be segregated for storage and, when
13 placed in a secondary container, that container shall be labeled
14 with the words “Pathology Waste,” “PATH,” or other label
15 approved by the department on the lid and sides, so as to be visible
16 from any lateral direction, to ensure treatment of the waste pursuant
17 to Section 118222.

18 (6) Pharmaceutical waste, as defined in paragraph (3) of
19 subdivision (b) of Section 117690, shall be segregated for storage
20 in accordance with the facility’s medical waste management plan.
21 When this waste is prepared for shipment offsite for treatment, it
22 shall be properly containerized for shipment in compliance with
23 United States Department of Transportation and United States
24 Drug Enforcement Agency (DEA) requirements.

25 ~~(A) Pharmaceutical wastes classified by the DEA as “controlled~~
26 ~~substances” shall be disposed of in compliance with DEA~~
27 ~~requirements.~~

28 ~~(B) Nonradioactive~~

29 *Nonradioactive* pharmaceutical wastes that are not subject to
30 the federal Resource Conservation and Recovery Act of 1976
31 (Public Law 94-580), as amended, and that are regulated as medical
32 waste are placed in a container or secondary container labeled with
33 the words “HIGH HEAT” or “INCINERATION ONLY,” or with
34 another label approved by the department, on the lid and sides, so
35 as to be visible from any lateral direction, to ensure treatment of
36 the biohazardous waste pursuant to Section 118222.

37 (7) A person may consolidate into a common container, which
38 may be reusable, sharps waste, as defined in paragraph (4) of
39 subdivision (b) of Section 117690, and pharmaceutical wastes, as

1 defined in paragraph (3) of subdivision (b) of Section 117690,
2 provided that both of the following apply:

3 (A) The consolidated waste is treated by incineration or
4 alternative treatment technologies approved to treat that waste
5 pursuant to paragraph (1) or (3) of subdivision (a) of Section
6 118215 prior to disposal. That alternative treatment shall render
7 the waste unrecoverable and nonhazardous.

8 (B) The container meets the requirements of Section 118285.
9 The container shall be labeled with the biohazardous waste symbol
10 and the words “HIGH HEAT” or “INCINERATION ONLY,” or
11 with another label approved by the department, on the lid and
12 sides, so as to be visible from any lateral direction, to ensure
13 treatment of the waste pursuant to this subdivision.

14 (b) To containerize medical waste being held for shipment
15 offsite for treatment, the waste shall be labeled, as outlined in
16 subdivision (a), on the lid and sides of the container.

17 (c) When medical waste is containerized pursuant to
18 subdivisions (a) and (b) there is no requirement to label the
19 containers with the date that the waste started to accumulate.